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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,079	04/22/2004	Stephen Bennett Elliott		6024

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Stephen Bennett Elliott
702 Buffalo Springs Drive
Allen, TX 75013

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,079

Applicant(s)

ELLIOTT, STEPHEN BENNETT

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20051201.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/10/2006 has been entered.

Election/Restrictions

2. Claims 29-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/14/2006.
3. Applicant's election without traverse of claims 19-28 in the reply filed on 7/14/2006 is acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find support in the originally filed disclosure of the "non-stationary exercise" limitation of claim 19. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3762

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 19-21, 27, and 28 are rejected under 35 U.S.C. 102(b) as anticipated by Vaschillo et al. (US 5,997,482, hereinafter "Vaschillo") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vaschillo in view of Kullok et al. (US 6,644,976, hereinafter "Kullok"). Vaschillo discloses the essential features of the claimed invention including the following:

In regards to claim 19, Vaschillo discloses a method comprising monitoring a heartbeat, determining a heart rate variability cycle, detecting positive and negative heart rate peaks, providing an exhale signal at the positive heart rate peak and an inhale signal at the negative heart rate peak (Fig. 3A and col. 3, lines 23-52). Please note that, because the subject is instructed to ensure that there is a zero phase shift between the HRV tracing and respiratory tracing, the subject performs the method of detecting the positive and negative peaks and the device provides the inhale and exhale signals by virtue of the patient seeing the tracings in Figure 3A and exhaling at the peak of the HRV cycle. In other words, the inhale and exhale signals are the peaks of the HRV cycle because the subject is instructed to match the phase angle of the two (cardiac and respiratory) tracings. With respect to the "non-stationary exercise" limitation, any movement of the body (including breathing) can be considered non-stationary exercise under its broadest reasonable interpretation because, for instance, breathing involves the movement of the thorax and can be considered exercise, such as in a patient recovering from respirator dependency.

Art Unit: 3762

8. Alternatively, Kullok teaches of promoting synergy between movement (such as exercise or breathing) and a physiological activity (such as heart rate) to promote or improve performance in various activities (col. 1, line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vaschillo's device by providing the device to a subject undergoing non-stationary exercise to promote or improve performance in the activity.

9. In regards to claims 20 and 21, because the HRV tracing is provided to the subject, the subject can see when the HRV cycle is stable/unstable, thus the exerciser is signaled when the HRV cycle is stable/unstable.

10. In regards to claim 27, the signal is a visual signal (Fig. 2).

11. In regards to claim 28, the inhale and exhale signals correspond to a cycle that is coherent (zero phase lag) with the HRV signal (col. 3, line 41).

12. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaschillo in view of Kullok. Vaschillo discloses the essential features of the claimed invention except for instructing the subject to obtain a stable HRV cycle before beginning exercise, providing an exercise tempo signal based on HRV, or disabling the inhale/exhale signals when transitioning from a first tempo to a second tempo. Kullok teaches of instructing the subject to obtain a stable HRV cycle before beginning exercise (col. 44, line 2) to allow accurate, stable measurement of the heart rate parameter; providing an exercise tempo signal (abstract) to promote or improve performance in various activities (col. 1, line 11); and allowing the heart to stabilize

Art Unit: 3762

when transitioning from a first tempo to a second tempo (col. 44, line 2) to avoid providing inaccurate movement signals to the subject. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vaschillo's invention by instructing the subject to obtain a stable HRV cycle before beginning exercise to allow accurate, stable measurement of the heart rate parameter; providing an exercise tempo signal to promote or improve performance in various activities; disabling the breathing signal when transitioning from a first tempo to a second tempo to avoid providing inaccurate breathing signals to the subject.

Response to Arguments

13. Applicant's arguments with respect to claims 19-28 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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GE
GEORGE R. EVANISKO
PRIMARY EXAMINER

10/5/06